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| 09/730,329      | 12/04/2000  | Varghese John        | 00228-US-NEW3       | 8197             |

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                    |  |
|------------------------------|--------------------------------------|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/730,329 | <b>Applicant(s)</b><br>JOHN ET AL. |  |
|                              | <b>Examiner</b><br>Chih-Min Kam      | <b>Art Unit</b><br>1656            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2006.  
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 6-10 and 22 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☒ Claim(s) 6-10 is/are allowed.  
 6) ☒ Claim(s) 22 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 6-10 and 22 are pending.

Applicant's amendment filed March 14, 2006 is acknowledged, and applicants' response has been fully considered. Claim 6 has been amended, claims 13 and 14 have been cancelled, and a new claim 22 has been added. Therefore, claims 6-10 and 22 are examined.

### **Withdrawn-Claim Objections**

2. The previous objection of claims 6, 7 and 10 is withdrawn in view of applicant's amendment to the claim, and applicant's response at page 9 in the amendment filed March 14, 2006.

### **Withdrawn-Claim Rejections - 35 U.S.C. § 112**

3. The previous rejection of claims 6, 8 and 9 under 35 U.S.C. § 112, second paragraph, is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 9-10 in the amendment filed March 14, 2006.

### ***Informalities***

The disclosure is objected to because of the following informalities:

4. The substituted specification recites specific fragments of beta-secretase (e.g., residues 46-419, 46-452, and 63-423; paragraphs [0007]-[0009])) and full length of beta-secretase (i.e., residues 1-501; paragraph [0010]) without providing the sequence identifier, it is not clear which sequence these residues refer to. Furthermore, the marked copy of the substituted specification is not consistent with the clean copy of the substituted specification, e.g., the marked copy does not delete the brief description of sequence listing.

***Objection to New Matter Added to Specification***

5. The substituted specification with deletion of brief description of the drawings, some sequences and brief description of sequence listing, filed June 21, 2004, and the amendment to the specification filed March 14, 2006 are objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The substituted specification recites specific fragments of beta-secretase (e.g., residues 46-419, 46-452, and 63-423; paragraphs [0007]-[0009]) and full length of beta-secretase molecule (residues 1-501; paragraphs [0010]) but deletes the corresponding sequence identifier. The sequence listing filed June 21, 2004 do not contain the amino acid sequence of the full length of human beta-secretase, and its coding nucleotide sequence. Thus, the sequences for fragments or full length of beta-secretase cited in the substituted specification would have different scope from the sequences in the original specification, because the original sequences refer to specific fragments of human beta-secretase (i.e., SEQ ID NO:2), while the sequences cited in substituted specification do not refer to a specific reference sequence (i.e., SEQ ID NO:2). In the amendment to the specification filed March 14, 2006, more paragraphs and sentences related to the nucleotide (original SEQ ID NO:1) and peptide sequence (original SEQ ID NO:2) of beta-secretase have been deleted, which also change the scope of beta-secretase in the original specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Response to Arguments

Applicants indicate the specification has been more extensively revised to delete paragraphs or sentences in which omitted sequences occurred. Thus, the specification no longer refers to the nucleic acids or peptides previously defined by SEQ ID NO. It is noted that the present claims are directed to compounds, and that the omitted sequence disclosure is not necessary to make the compounds. The compounds can also be used on beta secretase isolated from natural sources, as described in the specification, so the omitted sequences are not necessary for use of the claimed compounds either. In view of the additional deletions, it is respectfully submitted that the rejection is moot (page 9 of the response).

Applicants' response has been fully considered, however, the arguments are not found persuasive because of the following reasons. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. However, the substituted specification and the amendment filed March 14, 2006 have changed the scope of beta-secretase in the original specification by deleting the nucleotide and peptide sequence of human beta-secretase, and the claimed compounds are inhibitors of beta-secretase and are identified by assays of beta-secretase. Therefore, the changes in the substituted specification and the amendment filed March 14, 2006 introduce new matters.

***New Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 is indefinite because of the use of the term "the phenyl group". The term cited renders the claim indefinite, it is not clear which phenyl group the term refers to, e.g., the phenyl group in Phe-sta as Y, the phenyl group in Phg as Z, or the phenyl group in Phe or Phg as X. Claim 22 is also indefinite since the claim does not have a period "." at the end of the sentence.

### ***Conclusion***

7. Claim 22 is rejected; and claims 6-10 are free of art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner



**CHIH-MIN KAM**  
**PATENT EXAMINER**

CMK

May 18, 2006